

**UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MISSOURI
EASTERN DIVISION**

ANNE WEGMANN,)
)
 Plaintiff,)
)
 v.) No. 4:20-CV-00704 JAR
)
 ETHICON, INC., et al.,)
)
 Defendants.)

MEMORANDUM AND ORDER

This matter is before the Court on Plaintiff's Motion to Exclude Opinions and Testimony of Charles Butrick, M.D. (Doc. No. 43); and Plaintiff's Motion To Strike Defendants' Experts That Exceed The Five (5) Expert Limit Set Forth By Pre-Trial Order #328 and To Limit Defendants' Employees From Offering Expert Opinions (Doc. No. 69). The motions are fully briefed and ready for disposition.¹

I. Background

This matter was recently transferred to this Court from multi-district litigation ("MDL") in the United States District Court for the Southern District of West Virginia. In re Ethicon, Inc. Pelvic Repair Systems Products Liability Litigation, No. 2:12-md-2327 (S.D. W.Va.). The MDL involves claims of harm resulting from implantation of various polypropylene-based mesh products, including tension-free vaginal tape ("TVT"). On May 14, 2003, Plaintiff underwent implantation of Ethicon's TVT Retropubic Support System for treatment of stress urinary incontinence ("SUI"). The surgery was performed by Dr. Robert Feit in St. Louis, Missouri.

¹ On October 8, 2020, Plaintiffs filed a notice of supplemental authority in support of their motion to strike (Doc. No. 90), which the Court has considered.

Within one year of implantation, Plaintiff began to experience a number of physical problems; in 2015, she underwent surgery to remove the TVT. On November 10, 2014, Plaintiff filed a “Short Form Complaint,” incorporating the First Amended Master Long Form Complaint, against Ethicon and Johnson & Johnson (collectively “Ethicon”) in the MDL. Plaintiff alleges numerous causes of action against Ethicon, including negligence, strict liability, and fraud. (Doc. No. 1).

II. Motion to exclude opinions and testimony of Charles Butrick, M.D.

Ethicon has designated Charles Butrick, M.D., a urogynecologist and specialist in pelvic floor disorders, to provide case-specific expert opinions related to causation in this case. Plaintiff moves to exclude Dr. Butrick’s opinions and testimony as based on insufficient facts and unreliable methodology.

A. Legal standard

The admission of expert testimony in federal court is governed by Federal Rule of Evidence 702. A district court acts as a “gatekeeper” when screening expert testimony for relevance and reliability. Daubert v. Merrell Dow Pharm., Inc., 509 U.S. 579, 590-93 (1993); Russell v. Whirlpool Corp., 702 F.3d 450, 456 (8th Cir. 2012). To satisfy the reliability requirement, the party offering the expert testimony “must show by a preponderance of the evidence both that the expert is qualified to render the opinion and that the methodology underlying his conclusions is scientifically valid.” Barrett v. Rhodia, Inc., 606 F.3d 975, 980 (8th Cir. 2010) (quoting Marmo v. Tyson Fresh Meats, Inc., 457 F.3d 748, 757 (8th Cir. 2006)). To satisfy the relevance requirement, the proponent must show that the expert’s reasoning or methodology was applied properly to the facts at issue. Id.

The Court in Daubert emphasized that the inquiry required by FRE 702 is intended to be flexible. 509 U.S. at 594. The Daubert analysis was extended to all expert testimony, as opposed

to only “scientific” testimony. Kumho Tire Co., Ltd. v. Carmichael, 526 U.S. 135, 147 (1999). Due to the liberalization of expert testimony admission standards signaled by Daubert and its progeny, and the codification of this trend by FRE 702, the Eighth Circuit has held that expert testimony should be liberally admitted. Johnson v. Mead Johnson & Co., LLC, 754 F.3d 557, 562 (8th Cir. 2014) (citing United States v. Finch, 630 F.3d 1057, 1062 (8th Cir. 2011) (doubts about usefulness of expert testimony are resolved in favor of admissibility)); Robinson v. GEICO Gen. Ins. Co., 447 F.3d 1096, 1100 (8th Cir. 2006) (expert testimony should be admitted if it advances the trier of fact’s understanding “to any degree”); Lauzon v. Senco Prod., Inc., 270 F.3d 681, 686 (8th Cir. 2001) (FRE 702 “clearly is one of admissibility rather than exclusion”) (quotations omitted). As long as the expert testimony rests upon “good grounds, based on what is known,” it should be tested by the adversary process with competing expert testimony and cross-examination, rather than excluded at the outset. Id. (citing Daubert, 509 U.S. at 596). Exclusion of an expert opinion is proper “only if it is so fundamentally unsupported that it can offer no assistance to the jury.” Wood v. Minnesota Mining & Mfg. Co., 112 F.3d 306, 309 (8th Cir. 1997) (citation and quotation marks omitted).

B. Discussion

Plaintiff seeks to exclude several of Dr. Butrick’s opinions: (1) “general opinions in [Plaintiff’s] case that are not specific to this Plaintiff” (Doc. No. 44 at 5-7); (2) opinions “based solely upon his ‘clinical experience’ and ‘position statements’” (id. at 7-8); (3) opinions regarding the appropriateness of treatment rendered by Plaintiff’s treating physicians, Dr. Feit and Dr. Veronikis, and whether they deviated from the applicable standard of care (id. at 8-13); (4) opinions identifying certain alternative causes for Plaintiff’s alleged injuries, such as hypertonic pelvic floor dysfunction, pelvic floor myalgia, low back/hip pain, and degenerative

disc disease (*id.* at 13-17); and (5) opinions offered during Dr. Butrick's deposition that were purportedly not contained in his expert report (*id.* at 17-19). The Court will address each challenged opinion in turn.

(1) General opinions

First, Plaintiff seeks to exclude Dr. Butrick's general opinions that are not specific to Plaintiff, including, *inter alia*, his opinions that the TVT is the "gold standard" for treatment of SUI; that the benefits of the TVT outweigh the risks; that the TVT does not have any design defects and is safe and effective; that the Instructions for Use ("IFU") for the TVT is "not misleading and adequately warned surgeons of potential complications;" and that there are and were no safer alternative designs compared to the TVT for treatment of SUI. (Case Specific Report of Dr. Charges Butrick, M.D. ("Butrick Report"), Doc. No. 43-1 at 3-4, 18).

In response, Ethicon states that Dr. Butrick has not been designated as a general expert in this case and will not offer any general opinions related to the TVT device at trial. (Doc. No. 46 at 2). For this reason, Plaintiff's motion to exclude Dr. Butrick's general opinions will be denied as moot.

(2) Opinions based on solely on "clinical experience" and "position statements"

Next, Plaintiff challenges the reliability of certain of Dr. Butrick's opinions on the grounds that they are based not upon scientific testing, peer-reviewed literature, medical publications or studies, but rather his "clinical experience" and "position statements" from medical societies such as the American Urogynecologic Society (AUGS), American Congress of Obstetrics and Gynecologists (ACOG), or American Urological Association (AUA). Dr. Butrick references these position statements throughout his report:

[The majority of professional societies] have all endorsed full length polypropylene slings as safe and effective, deeming them the current standard of

care that is supported by the majority of the pelvic floor surgical community. As recent as 2018, AUGS/SUFU updated their joint position statement, affirming that ‘polypropylene material as safe and effective for surgical implants, that the MUS is the most extensively studied anti-incontinence procedure in history and that the MUS represented the most important advancement in the treatment of [SUI] in the last 50 years ... All of these statements reflect not only long term data and medical literature I have reviewed, but also are indicative of my clinical experience with these products.” (Butrick Report at 4).

“The ACOG guidelines concerning patients who present with symptoms that are much greater than the actual degree of prolapse mandates other etiologies to the symptoms should be considered.” (Id. at 10).

When a physician is asked to evaluate a patient for possible stress incontinence the AUA have provided basic guidelines for the evaluation that Dr. Feit did not follow” (Id.).

“The AUA guidelines go on to describe that urodynamic studies should be done if” (Id. at 10-11).

“Dr. Feit was below the standard of care with the lack of any evaluation of [Plaintiff’s] bladder symptoms prior to the performance of the sling procedure. He did not obtain the important history of pre-existing bladder infections. He was fully aware of the problem of voiding dysfunction and urgency, yet he did not evaluate any of these symptoms – which goes against the guidelines of the AUA.” (Id. at 17).

“The AUA guidelines were not met as stated previously in this report ... The basic evaluation as outlined by the AUA, SUFU and ACOG would be to perform a standing stress test while reducing the prolapse into a normal position to evaluate a patient for occult stress incontinence. This was never done.” (Id. at 19-20).

Plaintiff seeks to preclude Dr. Butrick from offering any legal opinion or conclusion based on his reliance on these statements because they are scientifically unreliable and litigation driven.

The Court agrees with Plaintiff that Dr. Butrick cannot represent to the jury that the various position statements referenced in his expert report embody a legal conclusion or a standard of care. See In re C. R. Bard, Inc., Pelvic Repair Sys. Prod. Liab. Litig., No. MDL 2187, 2018 WL 4220674, at *4 (S.D.W. Va. Sept. 5, 2018) (citing United States v. McIver, 470 F.3d 550, 572 (4th Cir. 2006) (“[O]pinion testimony that states a legal standard ... is generally

inadmissible.”)). Therefore, to the extent Dr. Butrick is relying on these statements for the “standard of care” or the safety and efficacy of polypropylene slings generally, Plaintiff’s motion will be granted and his opinions are excluded. However, to the extent Plaintiff seeks to exclude any of Dr. Butick’s opinions merely because he relied, in part, on the position statements, her motion is denied. “The unreliability of one source used by an expert in reaching his opinion does not call for the exclusion of that opinion altogether, assuming the expert considered other reliable sources in his methodology.” Id. Plaintiff’s challenge to Dr. Butrick’s opinions, based on the position statements, may be addressed on cross-examination.

(3) Opinions that Plaintiff’s treating physicians deviated from the applicable standard of care

In his report, Dr. Butrick opines that Plaintiff’s implanting physician, Dr. Feit, deviated from the applicable standard of care in connection with his treatment of Plaintiff by failing to conduct a sufficient diagnostic evaluation of her urinary complaints prior to recommending the TVT. (Butrick Report at 10-18). Similarly, Dr. Butrick opines that Dr. Veronikis, who performed Plaintiff’s revision surgery, deviated from the applicable standard of care by recommending and performing a surgical excision of the TVT based on a preoperative diagnosis of urinary retention without performing an adequate pre-implant evaluation of her voiding dysfunction, and by failing to follow-up with her postoperatively to determine if the voiding dysfunction had improved. (Id. at 16).

Plaintiff challenges these opinions as *ipse dixit* testimony, based solely on Dr. Butrick’s review of Plaintiff’s medical records. She argues that because Dr. Butrick never discussed Plaintiff’s symptoms and treatment with either of her treating physicians and never examined her, his opinions are speculative and thus unreliable under Daubert. In response, Ethicon emphasizes that Dr. Butrick relied upon the medical records produced by Drs. Feit and Dr.

Veronikis, AUA Guidelines and medical literature setting forth standards and recommendations for the evaluation and surgical treatment of SUI, as well as his own clinical experience. As such, his opinion that Drs. Feit and Veronikis deviated from the standard of care is supported by a reliable scientific methodology.

Expert witnesses are often called upon to sift through conflicting testimony and data to arrive at an opinion. Such determinations of judgment, provided they are well-reasoned and explained, do not render expert testimony inadmissible. Hershberger v. Ethicon Endo-Surgery, Inc., No. 2:10-CV-00837, 2012 WL 524442, at *4 (S.D.W. Va. Feb. 15, 2012). Upon review of the parties' respective arguments, the Court is satisfied that Dr. Butrick's report sufficiently explains how he formulated his opinions and that he relied on sufficient facts and data. That Dr. Butrick chose to credit some facts contained in the treating physicians' reports and testimony but not others, goes to the weight of his opinion testimony, not its admissibility, and may be challenged by offering competing testimony or through cross-examination. Chrastecky v. C. R. Bard, Inc., No. A-19-CV-1240-LY-SH, 2020 WL 748182, at *4-5 (W.D. Tex. Feb. 14, 2020). Accordingly, Plaintiff's motion will be denied on this point.

(4) Opinions identifying alternative causes for Plaintiff's alleged injuries

Plaintiff next argues that Dr. Butrick should be precluded from opining that Plaintiff's voiding/hypertonic pelvic floor dysfunction and pelvic floor myalgia caused her recurrent UTIs and that her alleged myofascial pain, low back pain, degenerative disc disease and hip pain caused her pelvic symptoms because he failed to conduct a sufficient differential diagnosis.

Differential diagnosis is a scientific technique that essentially involves the process of considering and then ruling out each alternative cause of a plaintiff's claimed injury. Chrastecky, 2020 WL 748182, at *4-5 (citation omitted). Dr. Butrick explained that in reaching his opinions,

he performed a differential diagnosis by reviewing Plaintiff's medical records in light of the different possible etiologies, "including but not limited to the possibility that it could be the mesh sling in this case." He also called upon his years of experience as a urogynecologist, as a reviewer of multiple medical journals, and as the past president of a pelvic pain society. (Deposition of Charles Butrick, M.D. ("Butrick Depo."), Doc. No. 43-2 at 83:17-85:18).

Plaintiff argues that Dr. Butrick's opinions are unreliable for several reasons. First, he did not perform any physical examinations of Plaintiff or review any TVT pathology specimens. Second, he did not consider the medical records and deposition testimony indicating that Plaintiff's UTIs increased in frequency following implantation of the TVT and lessened in frequency after removal of the TVT. Third, he did not consider that the "cording" of the TVT mesh caused Plaintiff's recurrent UTIs. And lastly, none of her treating physicians actually diagnosed her with hypertonic pelvic floor dysfunction and pelvic floor myalgia. Plaintiff also argues that Dr. Butrick is unqualified to opine that her alleged low back pain, degenerative disc disease, and hip pain caused her pelvic symptoms since he is not a board-certified orthopedic surgeon.

Ethicon is correct that a physician may reach a reliable differential diagnosis without personally performing a physical examination, particularly where, as here, the physician reaches his opinion by studying the records of other medical providers who examined the plaintiff. See Eghnayem v. Bos. Sci. Corp., 57 F. Supp. 3d 658, 702 (S.D.W. Va. 2014) (citing cases). Thus, Dr. Butrick's failure to physically examine Plaintiff does not, in itself, render his differential diagnostic unreliable. Furthermore, an expert's lack of specialization goes to the weight of the testimony, not its admissibility. Chrastecky, 2020 WL 748182, at *9.

The remainder of Plaintiff's challenges concern the accuracy of Dr. Butrick's differential diagnosis and thus go to the weight of his testimony, not its admissibility. Eghnayem, 57 F. Supp. 3d at 703. As noted above, the Court's role in reviewing a Daubert objection is to conduct "a preliminary assessment of whether the reasoning or methodology underlying the testimony is scientifically valid." Daubert, 509 U.S. at 592. Here, Dr. Butrick included a detailed summary and discussion of Plaintiff's medical records in his expert report, considered possible causes for her current symptoms, and concluded that:

[Plaintiff] originally complained to her gynecologist of severe pressure, urgency and voiding dysfunction; she did not report awareness of a bulge or stress incontinence. She never reported bulge symptoms prior to her prolapse surgery. [Plaintiff] never reported stress incontinence, however, she did report urgency and voiding dysfunction and later described problems with repeated bladder infections that started long before the sling was ever done. Despite this Dr. Feit recommended that she should have a sling. In short, her problems were not caused by a mesh product that was not studied enough or was designed inappropriately.

(Butrick Report at 21). This is a reliable methodology under Daubert. Tyree, et al. v. BSC, 54 F. Supp.3d 501, 566 (S.D. W.Va. Oct. 17, 2014). Furthermore, an expert's failure to completely "rule out" a possible alternative cause of a plaintiff's injury does not necessarily lead to exclusion under Daubert, "unless the expert can offer *no* explanation for why [he] has concluded an alternative cause ... was not the sole cause." Priddy v. C. R. Bard, Inc., No. 2:13-cv-10318, 2018 WL 662500, at *2 (S.D. W. Va. Feb. 1, 2018) (quoting Westberry v. Gislaved Gummi AB, 178 F.3d 257, 265 (4th Cir. 1999) (emphasis in the original)). To the extent there are records that Plaintiff contends were not adequately considered, or alternative causes not included in the differential diagnosis analysis, this can be addressed through cross-examination and competing testimony at trial. Accordingly, Plaintiff's motion will be denied on this point.

(5) New opinions not contained in Dr. Butrick's expert report

Finally, Plaintiff argues that Dr. Butrick should be precluded from opining on topics that were not disclosed in his expert report, specifically that pelvic floor hypertonic dysfunction and myofascial pain disorder caused Plaintiff's chronic pelvic pain. Plaintiff argues that Dr. Butrick offered these new opinions at his deposition on July 29, 2019, several weeks after the June 24, 2019 deadline for expert disclosures. Ethicon responds that Dr. Butrick's deposition testimony is not "new" opinion testimony; rather, this testimony merely supports and further explains the opinions set forth in his expert report. In reply, Plaintiff notes that her alleged conditions of hypertonic dysfunction and pelvic floor myalgia were only offered as causes for her UTIs or bladder infections, voiding dysfunction and urgency, and not for chronic pelvic pain. (See Butrick Report at 11, 13-14, 16-17). Indeed, it was Dr. Butrick's testimony that "issues of pain" were not "a major component of my case-specific report." (Butrick Depo. at 20:22-21:14).

Under Rule 26, expert reports must contain "a complete statement of all opinions the witness will express and the basis and reasons for them." Fed. R. Civ. P. 26(a)(2)(B)(i). Therefore, an expert's testimony generally is limited to his or her report produced in accordance with Rule 26(a)(2)(B), and to explanations "that are a reasonable extension of his report." Chrastecky v. C. R. Bard, Inc., No. A-19-CV-1240-LY-SH, 2020 WL 748182, at *8 (W.D. Tex. Feb. 14, 2020). Accordingly, Plaintiff's motion will be granted on this point and Dr. Butrick's testimony at trial will be limited to the opinions and statements in his report regarding pelvic floor hypertonic dysfunction and myofascial pain disorder as the cause of Plaintiff's recurrent UTIs.

C. Conclusion

For these reasons, Plaintiff's motion to exclude Dr. Butrick's opinions and testimony will be granted in part and denied in part.

III. Motion to strike Ethicon's experts that exceed the five-expert limit and to limit Ethicon's employees from offering expert opinions

On February 4, 2019, the MDL court entered Pretrial Order 328 in all Wave 11 cases, including Plaintiff's case. With respect to limitations on experts, the Order provides as follows:

The parties may conduct general and specific expert discovery on all products at issue in this Wave. In light of the products involved in this Wave, the likelihood of overlap in expert opinion from one case to another (except as to specific causation) and the need to streamline discovery in these cases, **the plaintiffs and each defendant are limited to no more than five experts per case (exclusive of treating physicians).**

(Doc. No. 14 at ¶ 3a.) (emphasis in the original).

On June 24, 2019, Ethicon served Plaintiff with its Designation and Disclosure of General and Case Specific Expert Witnesses Pursuant to Pretrial Order. (Doc. No. 70-1). Ethicon designated six (6) retained experts: Dr. Charles Butrick; Dr. Michael Woods; Dr. Peter Sand; Dr. Maria Abadi; Dr. Shelby Thames; and Mr. Timothy Ulatowski², and sixteen (16) non-retained, non-treating physicians, experts: Dr. Piet Hinoul; Dr. Axel Arnaud; Dr. David Robinson; Dr. Aaron Kirkemo; Dr. Charlotte Owens; Dr. Dan Smith; Dr. James Hart; Dr. Martin Weisberg; Dr. Rich Isenberg; Dr. Jessica Shen; Dr. Charles Nager; Judith Gauld; Dr. Tom Divilio; Katrin Elbert, Ph.D.; Gene Kammerer; and Thomas A. Barbolt, Ph.D., D.A.B.T. According to Plaintiff, these Ethicon employees have routinely been disclosed as non-retained experts in most, if not all, transvaginal mesh cases involving Ethicon products.

Plaintiff filed the instant motion asking the Court to limit Ethicon's retained and non-retained experts to five as set forth in Pretrial Order 328, strike any expert witnesses that exceed

² Ethicon disclosed expert Timothy Ulatowski (Regulatory) as an alternative retained expert that it would have used in place of one of their retained experts but for the MDL Court's ruling excluding FDA evidence. (Doc. No. 70-1 at 2; Doc. No. 79 at 3 n.2). There appears to be an understanding between the parties that Mr. Ulatowski will not offer opinions or testimony unless the MDL Court's FDA rulings are revisited or reversed. (Doc. No. 82 at 7 n.2). Thus, to the extent Plaintiff's motion seeks to have Mr. Ulatowski stricken, the motion will be denied.

that limit consistent with prior rulings by the transferor court, and limit Ethicon's employees from offering expert testimony. After consideration of the parties' arguments, the Court will grant Plaintiff's motion to the extent it seeks to exclude Ethicon's retained and non-retained experts in excess of five. The Court notes that the MDL court has uniformly enforced the five-expert limit, ruling that “[f]rom the beginning of these MDLs, the court ordered in every single docket control order that ‘the plaintiffs and each defendant are limited to no more than five experts per case (exclusive of treating physicians).’ ” See Ethicon, Inc. Pelvic Repair Systems Prod. Liab. Lit., No. 2:12-md-02327, [Doc. No. 9118] (S.D. W.Va. May 7, 2020) (Order) (Goodwin, J.) (Doc. No. 70-3); Ethicon, Inc. Pelvic Repair Systems Prod. Liab. Lit., No. 2:12-md-02327, [Doc. No. 9119] (S.D. W.Va. May 11, 2020) (Order) (Goodwin, J.) (Doc. No. 70-4); Lankston v. Ethicon, Inc., et al., 2:12-cv-00755, [Doc. No. 148], (S.D. W.Va. Jan. 12, 2017) (Order) (Goodwin, J.) (Doc. No. 70-5); In re: Ethicon, Inc. Pelvic Repair Systems Prod. Liab. Lit., No. 2:12-md-02327, [Doc. No. 8902], at *2 (S.D. W.Va. Nov. 18, 2019) (Order) (Goodwin, J.) (Doc. No. 70-6); In re: Boston Scientific Corp. Pelvic Repair Systems Prod. Liab. Lit., No. 2:12-md-02326, [Doc. No. 8379], at *1 (S.D. W.Va. Nov. 22, 2019) (Order) (Goodwin, J.) (Doc. No. 70-7). Most recently, a transferee court faced with arguments identical to those submitted by the parties in this case granted plaintiffs' motion to strike and rejected Ethicon's arguments in opposition. See Kelly, et al. v. Ethicon, Inc., et al., No. 6:20-cv-2036-CJW-MAR, [Doc. No. 91] (N.D. Iowa Oct. 7, 2020).

Accordingly,

IT IS HEREBY ORDERED that Plaintiff's Motion to Exclude Opinions and Testimony of Charles Butrick, M.D. [43] is **GRANTED in part** and **DENIED** in part in accordance with the rulings herein.

IT IS FURTHER ORDERED that Plaintiff's Motion To Strike Defendants' Experts That Exceed The Five (5) Expert Limit Set Forth By Pre-Trial Order #328 And To Limit Defendants' Employees From Offering Expert Opinions [69] is **GRANTED**.

Dated this 8th day of October, 2020.



JOHN A. ROSS
UNITED STATES DISTRICT JUDGE